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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,058	12/13/2001	Mingxian Huang	471842001600	5669
25225 7590 03/07/2007 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			EXAMINER LAM, ANN Y	
			ART UNIT	PAPER NUMBER
			1641	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/07/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/022,058	<b>Applicant(s)</b> HUANG ET AL.	
	<b>Examiner</b> Ann Y. Lam	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 31-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

Applicants' pre-appeal brief filed January 20, 2007 has been considered. Upon reconsideration, prosecution has been reopened.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitation "said polymer coating" in line 2. There is insufficient antecedent basis for this limitation in the claim. The claims from which claim 22 depends only refer to a coating film and do not recite a polymer. Claim 22 will be interpreted as if "said polymer coating" is referring to the coating film. (Moreover, the claim will be interpreted to mean that the particulate particles comprise between about 0.1% and about 99.99% of the volume of the coating film.)

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-7, 9, 11, 21, 23, 25, 28, 29, 31-35 are rejected under 35

U.S.C. 102(e) as being anticipated by Burdon et al., 6,572,830.

As to claim 1, Burdon et al. teach a microfluidic device with fluid passageways, wherein the microfluidic device is formed by sheet layers that include particles such as ceramic particles, glass particles and glass-ceramic particles (col. 3, lines 19-20). Burdon et al. also teach that the sheet may additionally include additives such as plasticizers and dispersants (col. 7, lines 1-3). See also column 26, line 63 – column 27, line 3, disclosing the formation of a channels using the sheet layers. The surface of one of the sheet layers (e.g., 1208 in fig. 34) is deemed to be the claimed surface, and an adjacent sheet layer (e.g. 1206 in fig. 34) on top is deemed to be the claimed coating film coated on the claimed surface and defining in part the channel structure (the channel is at 1218 in fig. 34). The plasticizer or dispersant is deemed to be the claimed material, and the glass particles are deemed to be the particulate particles heterogeneous with the claimed material, and are wholly or partially imbedded within the claimed material. The microfluidic device is deemed to be a microchip because of its

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small size and because it has structures that provides for performing an assay, as does a microchip.

As to claims 2 and 23, the surface comprises at least in part glass (col. 6, line 67.)

As to claims 3 and 35, the surface comprises an electromagnetic element (see col. 26, line 66 – col. 27, line 5.)

As to claim 5 and 11, the surface (sheet layer) is between about 0.1 micrometers and about 10 centimeters or 10 millimeters in thickness (see col. 7, lines 3-4, disclosing that the sheet is 50 to 250 microns, i.e., micrometers, thick.)

As to claims 6 and 7, the coating film comprises a hydrophobic or hydrophilic polymer (col. 7, lines 1-2, disclosing a polymer binder.)

As to claims 9 and 25, the coating film is biocompatible (col. 22, lines 13-16.)

As to claim 21, the particulate particle is wholly imbedded within the coating film (since the sheet is made up of the particulate particle, and thus some of the particles will be wholly imbedded within the sheet.)

As to claim 28, the channel structure (e.g., 1218, in fig. 34) comprises open or closed channels.)

As to claim 29, at least a portion of the channel structure is defined by said surface (col. 26, lines 66 -67.)

As to claim 31, at least a portion of the channel structure is defined by selective polymerization of the coating film (col. 22, lines 27-30-43, disclosing UV-polymerizable adhesive.)

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As to claim 32, the channel structure is considered to be forming an island, as it is distinct from other structures of the microfluidic device.

As to claim 33, the cross section of the channel is rectangular (see 1218 in fig. 34.)

As to claim 34, the channel structure is either linear or curved since it must be one or the other (see also fig. 34, showing a cross section of the channel, wherein at least the cross section dimensions are linear).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 10, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burdon et al., 6,572,830.

Burdon et al. disclose the invention substantially as claimed (see claim 1 above).

As to claims 4 and 10, Burdon et al. do not teach that the surface or the coating film is between about 10 micrometers and about 20 centimeters in length or width.

Burdon et al. teach that the sheet may be 50 to 250 microns (micrometers) thick (col. 7, lines 3-4). (While thickness can be considered a width, the dimensions of which are disclosed by Burdon et al., Examiner however will interpret width as Applicants intended, i.e., not the thickness.)

However, Burdon et al. not only teach that the sheet may be 50 to 250 microns thick, but also that the typical channels have diameters ranging from under 100 microns to 500 microns (col. 7, lines 65-66.) Thus, Burdon et al. teach that the dimensions of the channels, which are formed by the sheet layers, of the microfluidic device are small. Moreover, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (MPEP 2144.05 IIA, citing *In re Aller*, 105 USPQ 233). In this case, Burdon et al. teach the general conditions of the claims, and the length or width of the claimed surface or coating film (equivalent to Burdon et al.'s sheet layers, respectively) being of the dimensions recited by Applicants are optimum or workable ranges and thus their discovery involves only routine skill in the art.

As to claim 22, Burdon et al. do not teach that the particulate particles comprise between about 0.1% and about 99.99% of the volume of the coating film. However, this is an optimum or workable range given the teachings of Burdon et al. as to the particles and sheet (deemed to be the claimed coating film), and thus its discovery involves only routine skill in the art.

As to claim 24, Burdon et al. do not teach the size of the particulate particles being in the claimed range. However, the claimed range is an optimum or workable range and thus its discovery involves only routine skill in the art.

Claims 12-20, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burdon et al., 6,572,830, in view of Kuhr et al., 6,294,392.

Burdon et al. discloses the invention substantially as claimed, except for the coating film comprising at least in part a biological group.

Kuhr et al. however teach a microfluidic biosensor for detecting target analyte in a sample by immobilizing binding partner probes specific to various analytes, using for example biotin/avidin technology, such that when a sample is flushed through the capillary, the analytes bind to the binding partners immobilized on the capillary wall and the rest of the sample is eluted from the capillary. The analyte is released and flushed past a detector (col. 2, lines 12-34.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide immobilized probes along a microfluidic channel taught by Kuhr et al. in the Burdon et al. microfluidic device, because Kuhr et al. teach that such a system provides for the benefit of binding to target analytes while allowing for the remainder of the sample to be eluted and to subsequently release the analyte for



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detection. Moreover the skilled artisan would have reasonable expectation of success because Burdon et al. also teach use of a sensor for detection, for example fluorescence or light scatter detection (col. 22, lines 54-65), and the dimensions of the microfluidic device of Kurh et al. is also in the micron size (col. 2, lines 57-62.)

As to claims 13 and 26, the biological group is specifically a protein or nucleic acid (col. 12, lines 41-45.)

As to claim 14, the biological group (i.e., protein or nucleic acid) is capable of interacting with a biological moiety or chemical moiety by electrostatic interactions, ionic interactions, hydrogen bonding or hydrophobic interactions.

As to claim 15, the biological group interacts with a biological moiety by nucleic acid-nucleic acid interactions (col. 12, 41-42.)

As to claim 16, the biological group is considered to be present substantially throughout the surface of said coating film, where the surface of the coating film is considered to be a section of a channel (see Kuhr et al., col. 2, lines 16-18.)

As to claims 17 and 27, the coating film comprises at least in part a chemical group (col. 12, lines 39-51.)

As to claim 18, the chemical group (e.g., nucleic acid or antibody) comprises small molecules (since the elements that make up nucleic acids and antibodies can be considered to be small molecules.)

As to claim 19, the chemical group (i.e., protein or nucleic acid) is capable of interacting with a biological moiety or chemical moiety by electrostatic interactions, ionic interactions, hydrogen bonding or hydrophobic interactions.

As to claim 20, the chemical group is considered to be present substantially throughout the surface of said coating film, where the surface of the coating film is considered to be a section of a channel (see Kuhr et al., col. 2, lines 16-18.)

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burdon et al., 6,572,830, in view of Kuhr et al., 6,294,392, and further in view of Kline, 5,384,241.

Burdon et al. discloses the invention substantially as claimed except for the coating film comprising at least in part polysaccharides.

Kuhr et al. however teach a microfluidic biosensor for detecting target analyte in a sample by immobilizing binding partner probes specific to various analytes, using for example biotin/avidin technology, such that when a sample is flushed through the capillary, the analytes bind to the binding partners immobilized on the capillary wall and the rest of the sample is eluted from the capillary. The analyte is released and flushed past a detector (col. 2, lines 12-34.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide immobilized probes along a microfluidic channel taught by Kuhr et al. in the Burdon et al. microfluidic device, because Kuhr et al. teach that such a system provides for the benefit of binding to target analytes while allowing for the remainder of the sample to be eluted and to subsequently release the analyte for detection. Moreover the skilled artisan would have reasonable expectation of success

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because Burdon et al. also teach use of a sensor for detection, for example fluorescence or light scatter detection (col. 22, lines 54-65), and the dimensions of the microfluidic device of Kurh et al. is also in the micron size (col. 2, lines 57-62.)

However, Kurh et al. do not teach polysaccharides as a probe for detection of target analytes. Kline however teach use of analyte-specific polysaccharides as well as oligonucleotide probes and antibodies for specifically binding to analytes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize analyte-specific polysaccharides as taught by Kline in the invention of Burdon et al. in view of Kuhr et al. because Kline teach that analyte-specific polysaccharides can also be used as probes which are generally taught by Kuhr et al. and the skilled artisan would have reasonable expectation of success given that Kline teach that analyte-specific polysaccharides can be used in assays for detection of target analytes in the same way that other specific binding moieties are used in assays.

### ***Response to Arguments***

Applicants' pre-appeal brief filed January 20, 2007 has been considered. Upon reconsideration, prosecution has been reopened. In view of the new grounds for rejections, Applicants' arguments are now moot.

Burdon et al. disclose the coating film as claimed by Applicants' and the biological or chemical materials on the microchannels (considered to be part of the film

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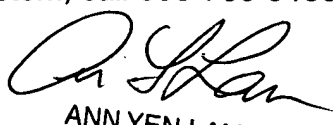
forming the microchannels) are taught by the secondary references and the motivation to provide such materials have been discussed above.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 2/23/07  
ANN YEN LAM  
PATENT EXAMINER